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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,477

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Brent Daniel Rogers

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EXAMINER

ZAREK, PAUL E

ART UNIT

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1617

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,477	<b>Applicant(s)</b> ROGERS ET AL.	
	<b>Examiner</b> Paul Zarek	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-23 is/are pending in the application.
- 4a) Of the above claim(s) 8-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/25/2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1, 3, 6, and 7 have been amended, Claims 21-23 have been added, and Claims 4 and 5 have been cancelled by the Applicant in correspondence filed on 02/25/2009. Claims 1-3 and 6-23 are currently pending. Claims 8-20 remain withdrawn as being drawn to a nonelected invention. Claims 1-3, 6, and 7, and newly added Claims 20-23 read on the elected invention and are examined herein. This is the second Office Action on the merits of the claim(s).

## **RESPONSE TO ARGUMENTS**

2. Applicants traversed the assignment of 10/31/2003 as the effective filing date of the instant application. Applicants submit that the prior-filed provisional application 60/423,119 contains 35 U.S.C. § 112, first paragraph, support for the instant invention. Applicants point to Example 1 and Claim 8 of the '119 application as supporting the instant application. Examiner respectfully disagrees. Neither Example 1 nor Claim 8 of the provisional '119 application indicates that glucosamine (GLCN) or N-acetyl glucosamine (NAG) is heat-processed. In Example 1, the GLCN or NAG was added to the melted marshmallow (heat-processed component) after the marshmallows were melted. There is no indication that the temperature of the melted marshmallow was between 160°F and 180°F when the GLCN or NAG was added. Moreover, the Example states that "[i]n this experiment, the samples were not heated to high temperatures" (pg 12, lines 22-23). Claim 8 is directed to a NAG-comprising sports drink. Examiner found no claim in the provisional '119 application which comprised both a baked and

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non-baked component, as alleged on pg 18 of the reply filed on 02/25/2009. Therefore, the effective filing date of the instant application remains 10/31/2003.

3. Claims 1-7 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is moot in light of Applicants' amendment to the claims.

4. Claims 1-7 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kern and Heisey (International Application No. WO 01/93847, provided in IDS) in view of Gunter (The Ultimate Southern Living Cookbook, 1999). Claims 1-3, 6, and 7 were amended. Claims 4 and 5 were cancelled. Applicants argue that the rejection under 35 U.S.C. 103(a) utilizing the combination of Kern and Heisey and Gunter no longer applies because these prior art do not teach or fairly suggest the limitations of the newly amended claims. The newly amended claims recite the limitation that the heat-processed component can be at any pH, was heated to between about 160°F and about 180 °F, and retains at least 70% of the initial GLCN and/or NAG after heat-processing. Applicants note that Kern and Heisey do not contemplate heating their glucosamine HCl-containing glaze, and that all of the glazes disclosed by Gunter that involve heating, involve heating to boiling (above 212°F). Applicants also submit that the GLCN compositions of Kern and Heisey require the disclosed foodstuff to comprise an acidic environment (e.g. pH<9), which is distinct from newly amended Claim 3, in which the pH is at least 9. Thus, Applicants contend that the combination of Kern and Heisey and Gunter does not read on the rejected claims. Examiner respectfully disagrees

5. Claim 1 of the instant application is drawn to a food composition comprising a baked component and a heat-processed component, which comprises GLCN and/or NAG. The limitations following "wherein" on lines 6-9 of Claim 1 are directed to a product-by-process.

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The “product” is a heat-processed component that comprises GLCN and/or NAG. The “process” is the method of adding GLCN and/or NAG to a mixture of any pH, heating said mixture to a temperature between about 160°F and about 180 °F, and having the resulting heated mixture retain at least 70% of the GLCN and/NAG as was present in the composition prior to heating. Product-by-process claims are not limited to the manipulations of the recited steps, they are only related to the structure. In this case, the structure is a heat-processed component comprising GLCN and/or NAG. “The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (MPEP § 2113). Gunter teaches glazes that are heat-processed. One of ordinary skill in the art could add the GLCN and/or NAG to the heat-processed component following heating, and after said component has cooled to a temperature amenable to GLCN and/or NAG addition. One of ordinary skill in the art would be motivated to add GLCN or NAG, given the therapeutic effects of these supplements. The resultant compound would be indistinguishable from the product-by-process recited in Claim 1.

6. The pH limitations recited in Claims 1 (any pH) and 3 (pH of at least 9) do not distinguish the instant application from the teachings of Kern and Heisey. Kern and Heisey teach a foodstuff comprising a first and a second component (pg 5). Applicants’ assertion that the GLCN of Kern and Heisey must be in an acidic environment to be stable. The examiner respectfully disagrees. Kern and Heisey state that the second component, which is acidic, “is a critical component which synergistically interacts with the first component to provide health

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benefits” (pg 11, para 1, emphasis added). The acidic component is necessary for the GLCN to exert its therapeutic effect. There is no mention of a pH requirement for the stability of the GLCN in the foodstuffs disclosed in Kern and Heisey. Therefore, the arguments are seen to be irrelevant to the basis of rejection under 35 USC 103 (a). For these reasons, the rejection of Claims 1-3, 6, and 7 under 35 U.S.C. 103(a) over Kern and Heisey in view of Gunter is maintained.

7. Newly added Claims 20-23 are examined on their merits and the following **FINAL** rejection is made.

***Claim Rejections - 35 USC § 103***

8. The text of Title 35, U.S.C. § 103 can be found in a prior Office action.

9. Claim 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kern and Heisey (above) in view of Gunter (above).

10. Newly added Claims 21-23 are drawn to a food composition comprising at least two components: (a) at least one baked component; and (b) at least one heat-processed component comprising GLCN and/or NAG, wherein the heat-processed component does not require a pH adjustment (Claims 21 and 22), is heated to a temperature between about 160°F and about 180°F (Claims 21 and 22), and retains at least 70% of the initial concentration of GLCN and/or NAG after heat processing (Claims 21-23).

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11. As mentioned above, the “wherein” clause indicates a product-by-process with respect to the heat-processed component. Thus, for the reasons mentioned above, Kern and Heisey in view of Gunter render Claims 21-23 *prima facie* obvious.

### ***Conclusion***

12. Claims 1-3, 6, and 7 remain rejected. Newly added Claims 21-23 are rejected.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/San-ming Hui/  
Primary Examiner, Art Unit 1617